

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 1 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE  
CERTAIN OPINIONS OF MICHAEL THOMAS MARGOLIS, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter “Defendants”) submit this memorandum in support of their motion to exclude certain opinions of Michael Thomas Margolis, M.D.

**INTRODUCTION**

Dr. Margolis is a pelvic surgeon and urogynecologist in California who has experience implanting and removing sling systems and who has rendered largely identical opinions on Defendants’ TVT and TVT-O devices.<sup>1</sup> (*See* Dr. Margolis’s curriculum vitae and expert reports, attached as Exhibits B-D).

Plaintiffs, however, hope to elicit testimony from Dr. Margolis that is well beyond his expertise, such as opinions related to product warnings and the knowledge and state of mind of the parties. Moreover, many of his general causation opinions are unreliable, lacking in acceptable methodology or scientific support, and are thus inadmissible under Federal Rule of

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<sup>1</sup> Two plaintiffs who were implanted with Defendants’ Prolift device have designated Dr. Margolis as a general expert in their cases. *See* Exhibit A. Dr. Margolis has not produced *any* expert reports on the Prolift device in this Wave, however, and he should therefore be excluded as an expert on Prolift in those cases on this ground alone.

Evidence 702, *Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579 (1993). Specifically, the Court should preclude Dr. Margolis from testifying about:

- **Opinions regarding Defendants' knowledge, state of mind and alleged bad acts.** This Court has consistently prohibited improper state-of-mind or legal-conclusion testimony, and should so in regards to Dr. Margolis's proposed testimony as identified herein.
- **Opinions regarding alleged inadequate product warnings.** Dr. Margolis has no experience in preparing product warnings, and is admittedly unfamiliar with federal regulations governing product IFU documents.
- **Opinions that amount to nothing more than historical commentary.** In referencing and reciting the contents of Defendants' internal documents, Dr. Margolis is acting as Plaintiffs' advocate rather than expert.
- **Opinions regarding product marketing.** Dr. Margolis admits he has no specialized expertise in product marketing.
- **Opinions related to the propriety of the use of TVT that have no reliable basis.**
- **Opinions that require biomaterials expertise.** As demonstrated in his Curriculum Vitae and deposition testimony, Dr. Margolis has no demonstrated biomaterials expertise.
- **Opinions incorporating unnecessary and prejudicial hyperbole.**
- **Opinions that have not be disclosed in his expert reports.**

## LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at \*1-3 (S.D.W. Va. July 8, 2014). The Supreme Court's decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), precludes "engagement of 'expert' witnesses whose intended role is more to argue the client's cause from the witness stand than to bring the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re:*

*Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Plaintiffs seek to do precisely that through the testimony of Dr. Margolis. While Dr. Margolis may be qualified to render opinions about pelvic surgery, he has no specialized knowledge or expertise that would substantially assist the jury as it relates to other areas.

**I. The Court should exclude Dr. Margolis’s opinions about Defendants’ knowledge, state of mind, and alleged bad acts.**

Throughout his reports, Dr. Margolis claims to have knowledge of various risks and about what information supposedly was available to Defendants. These claims are based on mere speculation and the testimony of others. Examples set forth in Dr. Margolis’s expert reports include the following:

- “These risks are well known now. Numerous Ethicon employees have testified that they were aware of the risks discussed above, including Ethicon Medical Directors Dr. Piel Hinoul, Dr. David Robinson, Dr. Martin Weisberg, and Axel Arnaud. Even at the time the TVT was launched, internal documents reflect that all of the risks associated with implanting a synthetic mesh such as the TVT were known.” (Expert Report of Dr. Michael Margolis on TVT (“TVT Report”) at 9; *see also* Expert Report of Dr. Michael Margolis on TVT-O (“TVT-O Report”) at 9).<sup>2</sup>
- “Physicians expect and rely upon a medical device manufacturer to truthfully report the known qualities and risks of its products [such as degradation and inflammation], and Ethicon failed to do so.” (TVT Report at 12; *see also* TVT-O Report at 12).
- “Despite having different mechanical characteristics, Ethicon did not tell doctors via the Instructions for Use for TVT that the laser cut mesh acted differently than the mechanical mesh.” (TVT Report at 18; *see also* TVT-O Report at 18).
- “Ethicon never informed physicians of [the] incompatibility [between mesh and vaginal tissue] and the potential adverse outcomes that could arise.” (TVT Report at 20; *see also* TVT-O Report at 20).
- “Particle loss was a known problem and . . . it contributed to further unwanted foreign body reaction.” (TVT Report at 22; *see also* TVT-O Report at 23).

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<sup>2</sup> Dr. Margolis’s reports on the TVT and TVT-O are essentially identical except that his TVT-O report contains an additional opinion on groin, leg, and lower body pain. (TVT-O Report at 21).

- “Ethicon possessed evidence that the risk of vaginal scarring was greater than disclosed in its IFU. (TVT Report at 22; *see also* TVT-O Report at 23).
- “Ethicon did not have any procedure or Professional Education program to teach doctors how to properly remove TVT mesh slings when known complications occurred.” (TVT Report at 23; *see also* TVT-O Report at 23).
- “Ethicon has more information from its worldwide database and experiences from sales representatives than anyone else regarding the most effective and safest methods to treat complications.” (TVT Report at 23; *see also* TVT-O Report at 24).
- “[T]he IFU does not inform physicians (who in turn cannot inform patients) of these known risks [of using the TVT on special patient populations].” (TVT Report at 24; *see also* TVT-O Report at 24).

There is nothing about Dr. Margolis’s training and experience as a pelvic surgeon that affords him special expertise or clairvoyance that would somehow enable him to testify about Defendants’ state of mind. *See, e.g., In re: Diet Drugs Prods. Liab. Litig.*, 2000 U.S. Dist. LEXIS 9037, at \*9 (E.D. Pa. 2000) (precluding the plaintiffs’ experts from testifying as to the defendants’ intent); *In re: Rezulin*, 309 F. Supp. 2d at 547 (“Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony”.); *BorgWarner, Inc. v. Honeywell Int’l, Inc.*, 750 F. Supp. 2d 596, 611 (W.D.N.C. 2010) (precluding a party’s expert witness from opining about a party’s intent). To the extent that Dr. Margolis’s opinions are based on his review of documents that Plaintiffs’ counsel selectively presented to him, these concern mere “lay matters which a jury is capable of understanding and deciding without the expert’s help.” *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

This court in *Lewis v. Ethicon*, No. 12-cv-4301, 2014 WL 186872 (S.D. W. Va. Jan 15, 2014), precluded Dr. Margolis from offering similar testimony. This court found that “expert opinions on Ethicon’s knowledge or state of mind are not helpful to the jury” and that “Dr. Margolis is qualified as a physician; he is not qualified by ‘knowledge, skill, experience, training or education’ to opine on Ethicon’s state of mind or knowledge.” *Id.* at \*15.

This Court also precluded another physician from offering similar testimony in *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D. W. Va. 2013). In that case, one of the plaintiffs' experts, Dr. Bob Shull, a urogynecologist like Dr. Margolis, intended to testify about "Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics." *Id.* at 610. This Court, however, found as follows:

While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions – assuming the opinions are otherwise admissible – Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. See, e.g., *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a classic jury question and not one for the experts.") (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, I FIND that Dr. Shull's opinions related to Bard's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics should be excluded.

*Id.* at \*611 (emphasis added); see also *Hershberger v. Ethicon Endo-Surgery, Inc.*, 2012 WL 52444287, at \*7-8 (S.D. W. Va. Feb. 15, 2012) (Johnston, J.) (excluding an expert from testifying as to product defect, where expert's opinion was not based on his experience or education, but rather was based on other experts' testimony and the defendant's corporate documents). This Court has continued to diligently adhere to these principles, directing counsel to "tailor expert testimony at trial" in accordance with these limitations. *Mathison v. Bos. Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at \*3 (S.D. W. Va. May 6, 2015).

For the same reasons that this Court previously precluded Dr. Margolis and Dr. Shull from testifying about such matters, the Court should also preclude Dr. Margolis from testifying about these matters in the present case.

## **II. The Court should exclude Dr. Margolis's opinions related to product warnings.**

Dr. Margolis offers numerous opinions regarding the alleged inadequacy of the TVT and TVT-O IFU documents, including his opinion that Ethicon did not adequately study the product and should have included "severity and frequency" rates of alleged complications in the IFU. (TVT Rep. at 21-23). But he has no expertise in medical device warnings or regulatory requirements. For example, Dr. Margolis asserts as follows:

- "The IFU . . . described [foreign body] response as 'transient. This is not consistent with what I have seen in my professional experience, nor with Ethicon's internal documents.'" (TVT Report at 10; *see also* TVT-O Report at 10).
- "[T]he TVT IFU states, incorrectly, that the mesh is inert and not subject to degradation. In my opinion, this statement is false and misleading to physicians and patients." (TVT Report at 11; *see also* TVT-O Report at 11).
- "Ethicon failed to inform physicians and patients that its mesh was susceptible to fibrotic bridging which could lead to painful erosions, infections, nerve injury, dyspareunia, the need for multiple surgeries, chronic inflammation and pain among other complications." (TVT Report at 13; *see also* TVT-O Report at 13).
- "In its IFU, Ethicon states that the mesh may 'potentiate infection.' As a treating physician, this statement is misleading." (TVT Report at 15; *see also* TVT-O Report at 15).
- "The TVT IFU is inadequate because it omits and understates the serious complications discussed above. It also fails to properly inform a physician how to treat a patient who has presented with the above complications." (TVT Report at 22; *see also* TVT-O Report at 22).
- "Ethicon possessed evidence that the risk of vaginal scarring was greater than disclosed in its IFU." (TVT Report at 22; *see also* TVT-O Report at 23).
- "The IFU Understates the Severity and Frequency of the Complications" (TVT Report at 23; *see also* TVT-O Report at 23).
- "The TVT IFU did not inform physicians about techniques to treat complications from TVT mesh." (TVT Report at 23; *see also* TVT-O Report at 24).
- "The TVT IFUs offer no guidance for physicians on use of the TVT mesh products in special patient populations). (TVT Report at 24; *see also* TVT-O Report at 24).

### **A. Dr. Margolis is not qualified to testify about product warnings.**

Dr. Margolis has no expertise whatsoever in products warnings. For instance, Dr. Margolis has never participated in the drafting of a warning or IFU for a medical device, and he has no familiarity with how Defendants developed, reviewed, and/or analyzed their IFUs. (Margolis *Lewis* (11/25/13) Dep. 123:18-124:1; 126:22-25, attached as Exhibit E; Margolis *Batiste* (11/26/13) Dep. 170:16-24, attached as Exhibit F).<sup>3</sup> In fact, he demonstrated his lack of knowledge by admitting that he does not know if the FDA requires that symptoms of an adverse reaction be identified in an IFU. (Margolis *Batiste* (11/26/13) Dep. 172:19-173:17). Instead, his opinions are based merely on the review of documents that Plaintiffs' counsel presented to him; a task that requires no expertise. (Margolis *Lewis* (11/25/13) Dep. 272:1-11).

It is well established that an expert's mere credentials are insufficient, and instead, the expert's qualifications must have a sufficient connection with the specific subjects at issue in the case. *See, e.g., Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion).

Thus, in *C.R. Bard*, this Court also precluded the plaintiffs' expert urogynecologist, Dr. Shull, from testifying about product warnings. 2013 U.S. Dist. LEXIS 78061 at \*39-40. There, Dr. Shull offered conclusory opinions about the defendant's product warnings, and he failed to "provide a reasonable basis for his opinions of what Bard should have done with respect to its opinions." *Id.* at \*39. According to the Court, "[t]his is likely the result of Dr. Shull's lack of expertise in the specific area of warnings and labels for medical devices . . . ." *Id.* Accordingly, the Court concluded that "[d]espite his stellar qualifications as a urogynecologist, Dr. Shull is

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<sup>3</sup> Dr. Margolis was deposed regarding his general opinions on TVT and TVT-O in the cases of *Lewis v. Ethicon, Inc.*, No. 2:12-cv-04301 (S.D. W. Va.) on November 25, 2013, and *Batiste v. McNabb, et al.*, No. DC-12-14350 (Dallas Cnty., Tex. Dist. Ct.), on November 26, 2013.

unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process.” *Id.* at \*40.

Here, as in that case, the Court should preclude Dr. Margolis from testifying about product warnings, because it is outside his area of expertise.

**B. Dr. Margolis has not set forth any reliable and trustworthy bases for his opinions.**

Furthermore, many of the claimed “complications” set forth on pages 7-8 of Dr. Margolis’s reports, of which he asserts that Defendants should have warned, have not been reliably attributed to TVT. *See, e.g.,* Margolis *Batiste* (11/26/13) Dep. 205:12-207:3 (failing to identify any studies showing that TVT was capable of clinically significant degradation). For example, Dr. Margolis criticizes Defendants’ mechanically cut mesh (MCM) as inferior to laser-cut mesh (LCM), in that LCM allegedly experiences less particle loss than MCM. (TVT Rep. at 16-18; TVT-O Rep. at 16-18). He initially testified that “eroded mesh particles” could be found in other parts of the body, but subsequently admitted they could not be found anywhere except the vaginal canal. (Margolis *Batiste* (11/26/13) Dep. 206:9-22). He admitted he had no clinical literature supporting his theory that degraded polypropylene mesh particles increase the inflammatory response. (Margolis *Batiste* (11/26/13) Dep. 206:23-207:3). Another court recently explained that such evidence was legally insufficient, citing the admission of Plaintiff’s expert “[Howard] Jordi . . . [that] there could be degradation from the polypropylene that would have no clinical significance in a patient, and there was no evidence as to how much the polypropylene would have to degrade before it caused injury to a patient.” *Johnson & Johnson v. Batiste*, 2015 WL 6751063, at \*6, \*9 (Tex. App.—Dallas Nov. 5, 2015, pet. pending). Because Dr. Margolis can cite no reliable bases for these theories, these opinions should be



excluded under *Daubert* and Rule 702 for lack of “sufficient underlying facts or data.” Fed. R. Evid. 702.

Dr. Margolis also opines that there is a risk of cancer associated with polypropylene. (TVT Rep. at 20; TVT-O Rep. at 20). Yet when questioned, Dr. Margolis admitted that he had no evidence to support this opinion. (*See Margolis Batiste* (11/26/13) Dep. 150:6-17 (Q: “Doctor, are you going to testify that polypropylene causes sarcomas or cancer in humans?” . . . A: “I don’t have any evidence to—to that effect. So no.”)). These opinions, too, are therefore inadmissible on the grounds that they lack “sufficient underlying facts or data.” Fed. R. Evid. 702.

### **III. The Court should exclude Dr. Margolis’s opinions that amount to a mere historical commentary.**

Many of Dr. Margolis’s opinions are also improper because they are nothing more than a cumulative historic commentary about Defendants’ alleged bad acts that have nothing to do with his expertise. As this Court has noted, such a rehashing of a fact narrative is improper. *Hines v. Wyeth*, 2011 WL 2680842, at \*5 (S.D. W. Va. 2011) (Copenhaver, J.) (excluding expert testimony in part because it “merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness”).

Such improper testimony includes Dr. Margolis’s opinions about Defendants’ alleged knowledge, state of mind, and product warnings, which the Court should also exclude for the reasons set forth above. Other examples of opinions beyond Dr. Margolis’s expertise that amount to an impermissible historical commentary include the following:

- “Numerous Ethicon employees have testified that they were aware of the risks discussed above, including Ethicon Medical Directors Dr. Piel Hinoul, Dr. David Robinson, Dr. Martin Weisberg, and Axel Arnaud.” (TVT Report at 9; *see also* TVT-O Report at 9);

- “Former Medical Director, David Robinson, testified that the pore size of mesh ‘[c]ould reduce, the tissue might not encapsulate . . . the tissue might not grow through the mesh. It can become encapsulated and then it could cause . . . a rejection of the mesh’ which could lead to erosion.” (TVT Report at 13; *see also* TVT-O Report at 13);
- “. . . Ethicon did not have any procedure or Professional Education program to teach doctors how to properly remove TVT mesh slings when known complications occurred” ((TVT Report at 23; *see also* TVT-O Report at 23); and
- Inadmissible hearsay that “[M]anufacturers of polypropylene resin stated that it should not be used in the human body” ((TVT Report at 23; *see also* TVT-O Report at 23); and

There is no basis for Dr. Margolis to rehash these alleged factual events, and his testimony should be excluded. *See United States v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) (“Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments”); *In re: Rezulin*, 309 F. Supp. 2d at 551 (excluding expert testimony intended merely to “provid[e] an historical commentary of what happened”); *Highland Capital Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y.2005) (“[A]n expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence”); *In re: Trasyolol*, 709 F. Supp. 2d 1323, 1346-47 (S.D. Fla. 2010) (excluding expert’s testimony, including expert’s references to defendant’s internal documents, finding that the expert was simply “Plaintiffs’ advocate rather than expert”); *In re: Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding portions of an expert’s report because it “presents a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory findings, and the deposition testimony of Merck employees”).

#### **IV. The Court should exclude Dr. Margolis’s opinions related to product marketing.**

The Court should preclude Dr. Margolis from rendering opinions related to product marketing. Specifically, on page 6 of his reports, Dr. Margolis describes Census Bureau data

and states that “[t]his population provides an attractive target for marketing campaigns by device manufacturers seeking to capture a high market share for devices used in the treatment of these conditions.”

Dr. Margolis, however, has no expertise whatsoever in marketing. Instead, he apparently hopes to provide, improperly, an “editorial about pharmaceutical companies putting sales and marketing before science...” *In re: Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 881 (E.D. Ark. 2008), *rev’d in part on unrelated grounds*, 586 F.3d 547, 571 (8th Cir. 2009). Therefore, his opinions are beyond his area of expertise and are unreliable and untrustworthy. *See In re: C.R. Bard*, 2013 U.S. Dist. LEXIS 78061 at \*46 (precluding Dr. Shull from offering similar opinions about product marketing).

**V. The Court should exclude Dr. Margolis’s opinions related to the propriety of the usage of TVT and TVT-O that have no reliable basis.**

Dr. Margolis has been a crusader against TVT, and many of his sweeping opinions are unreliable, demonstrate his bias, and should be excluded. During his previous depositions regarding his general opinions on TVT and TVT-O, Dr. Margolis made broad statements suggesting that TVT is ineffective, that the Burch procedure remains the “gold standard,” and that TVT should be pulled from the market. (*See, e.g., Margolis Batiste* (11/26/13) Dep. 82:16-23, 91:18-92:2, 116:9-118:21, 128:25-129:16). These opinions have no scientific basis, and certainly not a basis that passes *Daubert* scrutiny.

**A. No basis for claim that Burch procedure is gold standard.**

In his reports, Dr. Margolis made the sweeping statement that the Burch procedure remains the “gold standard.” (TVT Report at 1; TVT-O Report at 1). This opinion has no scientific basis, and certainly not a basis that passes *Daubert* scrutiny. Despite asserting that the traditional Burch sling is the “gold standard for stress urinary incontinence,” Dr. Margolis has

not been able to identify a single reference in his reliance list to support that assertion. (Margolis *Batiste* (11/26/13) Dep. 82:16-84:7). In fact, he acknowledged that there is “literature that identifies the mid urethral sling [such as TVT and TVT-O] as the current gold standard.” (*Id.* at 102:16-103:2).

**B. No basis for claim that TVT is ineffective.**

Dr. Margolis asserts in his reports that the TVT is “no more efficacious at treating stress urinary incontinence than other procedures that do not involve mesh.” (TVT Rep. at 25; TVT-O Rep. at 26). Furthermore, during his deposition, Dr. Margolis asserted that TVT is ineffective. However, when asked if he could “point to a study that says that the TVT is not effective” or any “peer reviewed published literature that says TVT has low success rates,” Dr. Margolis was unable to do so. (Margolis *Batiste* (11/26/13) Dep. 128:25-129:16).

**C. No basis for claims that Burch sling is more effective, has fewer complications or is less painful.**

Although Dr. Margolis testified that Burch slings are more effective than TVT and have “unparalleled high success rates” measuring 88%, he could not identify a single study that supports those conclusory assertions. (Margolis *Lewis* (11/25/13) Dep. 249:7-16, 281:17-282:20; Margolis *Batiste* (11/26/13) Dep. 120:18-121:21; *see also* Margolis *Lewis* (11/25/13) Dep. at 160:4-12 (failing to identify any data, studies, or surveys supporting his opinion that TVT is being used less often as a consequence of complication rates); *id.* at 190:24-191:7 (responding “[n]ot that I know of” when asked to identify any studies that “support your opinion that show a statistically significant increased risk of postoperative pain for the TVT compare to Burch or the fascial slings”); *id.* at 277:23-278:6 (failing to “identify rigorous comparative trials that you believe were done on the Burch and the pubovaginal sling”)).

This Court has routinely excluded opinions complication rates and general effectiveness where plaintiffs, as here, fail to provide sufficient scientific support for such generalized statements. *See Mathison*, 2015 WL 2124991, \*7-8 (excluding opinions of Dr. Margolis regarding failure rates where he failed to explain why he disagreed with contrary studies and discounted scientific studies and instead gave patients “the benefit of the doubt” as to complication rates). The same conclusion should be reached in this case.

**VI. The Court should preclude Dr. Margolis from rendering an opinion on biomaterial properties of mesh because he is not qualified to opine on them.**

The Court should preclude Dr. Margolis from rendering opinions on biomaterials, polypropylene degradation, chronic foreign body reaction, adequate pore size, adequate weight of polypropylene, and biocompatibility of polypropylene. Dr. Margolis’s reports touch upon all of these topics, and opine on the way in which a synthetic material interacts with living tissues—*i.e.*, the subject of biomaterials science. Yet, as his curriculum vitae plainly discloses, Dr. Margolis is *not* a biomaterials expert. *See Exhibit B, Curriculum Vitae.*

Indeed, Dr. Margolis is not qualified by education, training or experience to opine on biomaterials science issues, including, without limitation, polypropylene mesh degradation, collapse, and porosity. He does not have an engineering degree in materials science, nor has he attended classes in materials science when in training. *See Exhibit B, Curriculum Vitae.* He does not have a demonstrated background in polymer chemistry or biochemical or biomechanical engineering, and his disclosed background indicates that he has never performed any bench research with respect to polypropylene. *See id.* Nothing else in Dr. Margolis’s experience as a surgeon would inform his opinion that TVT or TVT-O mesh, a biomaterial, degrades in the human body. He has done no research on polypropylene and has not published any papers on it.

(Margolis *Lewis* (11/25/13) Dep. 133:7-12). His testimony is not only anecdotal, it also has no scientific verification.

When Dr. Margolis's qualifications to testify regarding the biomaterial properties of mesh have been challenged in the past, the plaintiff has conceded that he or she will not offer opinions on that topic. *See, e.g., Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 680 (S.D. W. Va. 2014) (upon defendant's challenge to Dr. Margolis's opinions as to "biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design, and marketing," "plaintiffs conceded that Dr. Margolis will not be offering these opinions at trial"). In other instances before this Court, plaintiffs have avoided a substantive response to this challenge, engaging in "intentional ambiguity", resulting in the MDL court excluding Dr. Margolis's testimony on biomaterials and biocompatibility, among other topics. *Mathison v. Bos. Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at \*9-10 (S.D. W. Va. May 6, 2015); *see also Winebarger v. Bos. Sci. Corp.*, 2015 WL 1887222, at \*11 (S.D. W. Va. Apr. 24, 2015) (same). The Court should do the same in this case.

Likewise, in other mesh litigation, the proffered experts' qualifications to opine about biomaterial properties such as degradation and porosity have been closely scrutinized and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.D. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties

of polypropylene” mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material). In the present case, Dr. Margolis’ lack of biomaterials expertise precludes him from testifying about the biomechanical properties of mesh.

Additionally, Dr. Margolis has no particular medical device design expertise that would otherwise qualify him to opine regarding the design of this medical device. There is no evidence that he has designed a mesh-based device, and he has not published any articles about device design. *See, e.g., Tyree v. Bos. Sci. Corp.*, No. 2:12-cv-08633, 2014 WL 5486694, at \*47 (S.D. W. Va. Oct. 29, 2014) (Dr. Blaivas not qualified to opine on product design; his experience removing SUI devices and observing complications during removal did not, alone, render him qualified to opine as to design; nor did his work in developing a different (rectus fascial sling) qualify him as an expert in the design of a medical device); *id.* at \*68 (allowing a different urogynecologist to testify about product design only because he had “performed sling product design work ‘namely, a polytetrafluoroethylene suburethral sling in the 1980s, along with . . . design theory work for AMS’”). Accordingly, his opinions regarding design defect are nothing more than speculation and should be excluded.

## **VII. The Court Should Prohibit Dr. Margolis From Engaging In Extreme Exaggeration And Hyperbole.**

Based on experience from past trials and depositions, Ethicon has learned that Plaintiff’s expert, Michael Thomas Margolis, M.D., peppers his testimony with extreme exaggerations and overstatements – hyperbole without probative value and which would only serve to inflame jurors and unduly prejudice Ethicon. As the examples below plainly show, Dr. Margolis should

be precluded from engaging in any such hyperbole before the jury pursuant to FED. RULE EVID. 403.

In the *Carlino* TVT case, for example, when asked whether a plaintiff will have additional complications attributable to her mesh, Dr. Margolis testified that she will “most certain[ly]” have another erosion or exposure, describing the scenario as follows: “There’s periods of dormancy and [then] the volcanoes blow, . . . . And I’m certain that that Krakatoa will blow again. . . . [This is the] natural history of slings. They lay dormant and then, like volcanoes, they erupt.” See Exhibit G, Margolis Dep. (Nov. 21, 2015) (*Carlino*) at 84:25 - 86:11. Comparing a woman’s vagina to an erupting volcano is an inflammatory analogy that does nothing to assist the jury in understanding the common concept of “recurrence”. The comparison has no unique probative value. The concept of a recurring injury that may lie dormant for periods of time is not complex and can be explained without comparing a woman’s vaginal mesh to a notorious volcano responsible for the deaths of tens of thousands of innocent people.

Other examples include Dr. Margolis describing particle loss in the *Batiste* trial by comparing it to dropping a glass “and it shatters all over the floor and you’ve got shards of glass all over the floor, that’s a real problem. If you plan on walking across the floor in bare feet. . . .” Exhibit H, Trial Transcript at 59:22-60:17, *Batiste v. Ethicon, Inc.*, No. DC-12-14350 (95<sup>th</sup> Judicial District, Dallas County, Texas) (Mar. 24, 2014). And in *Cavness*, another Texas state court case, Dr. Margolis acknowledged that in describing mesh removal he would have “definitely” told Ms. Cavness that “[i]t’s like trying to remove Rebar from cement without ruining or damaging the plumbing.” Exhibit I, Margolis Dep. (July 19, 2015) (*Cavness*) at 239:3-12; see also Exhibit J Margolis Dep. (July 26, 2015) (*Rabiola*) at 156:8-22 (describing mesh



within a woman's body like "rebar, it's set in place and it locks it into -- the fibrosis locks the mesh into place.").

These extreme descriptions and overstatements have no probative value and would only unfairly prejudice Ethicon in this trial. Accordingly, Ethicon moves this Court to preclude any such hyperbole by Dr. Margolis.

**VIII. The Court should preclude Dr. Margolis from rendering any other opinions that are not disclosed.**

Finally, the Court should preclude Dr. Margolis from rendering opinions that are not set forth in his expert reports and/or that are not supported by information disclosed in his reliance list included with his expert report. As he showed in his depositions on his general opinions on TVT and TVT-O, he has not felt so confined in the past. Under Fed. R. Evid. 26(a)(2)(B), an expert report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming them." (emphasis added). Thus, Plaintiffs may not elicit opinions from Dr. Margolis that are not included in his reports.

On a number of occasions during his depositions, Dr. Margolis also suggested that his opinions were based on unidentified reference materials that may or may not be disclosed in the reliance lists submitted with his reports. To the extent he intends to do so with the reports he has proffered on TVT and TVT-O in this proceeding, the Court should similarly preclude Dr. Margolis from testifying as to any opinions that are based on undisclosed evidence.

**CONCLUSION**

For the reasons set forth above, the Court should limit the parameters of Dr. Margolis's testimony consistent with the foregoing.

Respectfully submitted,

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JOHNSON & JOHNSON

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**CERTIFICATE OF SERVICE**

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones

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